In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR GENETIC RESEARCH

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1. PURPOSE

The purpose of this SOP is to outline requirements for review of proposal involving Genetic material.

2. SCOPE

The scope of this SOP is to outline requirements for review of proposal involving Genetic material.

3. INTRODUCTION

The role of genetic research is indispensable in the ever challenging fields of diagnosis and treatment of genetic disorders, infectious diseases and non-communicable diseases. Main areas of genetic research include:

3.1 Genetic testing
3.2 Gene therapy
3.3 Reproductive genomics
3.4 Genetic databanks and pharmacogenomics

Researchers and policy makers alike are continuously assessing the value of this research in terms of its utility and cost-effectiveness for public health. (WHO)

4. TERMS & DEFINITIONS

4.1 Genetics research is the scientific discipline concerned with the study of the role of genes in traits such as the development of disease. It has a key role in identifying potential targets for therapeutic intervention and also in understanding genetically based variations in response to therapeutic interventions.

4.2 “Genetic Material” means any tissue sample that can serve as a source of DNA or RNA; including blood, saliva and any other tissues or body fluids containing nucleated cells from which DNA can be isolated.

5. OBJECTIVES

To ensure genetic research applications are received effectively and efficiently.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails

7. EXPECTED OUTPUTS

7.1 Agenda

7.2 Record of applications received

8. KEY PERFORMANCE INDICATORS

8.1 No. of applications received

9. RESPONSIBILITY AND AUTHORITY

It is the responsibility of the PI to:

9.1 Clearly define the nature and scientific justification for the proposed study.

9.2 Describe all planned study activities including: recruitment procedures, eligibility criteria etc.

9.3 Clearly describe the statistical considerations.

9.4 Identify the risks and the known nature of the risks of the proposed genetic research, explain how the risks will be minimized, especially privacy and confidentiality protections measures to be put in place.

9.5 Justify his/her choice of population from which the study participants will be drawn. When vulnerable populations will be recruited into the study, the PI/applicant must provide an explanation as to why it is critical to conduct genetic research on these individuals.

9.6 Explicitly describe the genetic component of the study and the risks of the genetic analyses in the informed consent document and in the process of obtaining consent (refer to Appendix G: Format and Content of an Informed Consent Document for Genetic Studies for consent document recommendations).

9.7 Disclose all persons who would have access to identifiable data of study participants and whether the results of the analyses will be released to participants or others (e.g. physicians, parents, guardians).

9.8 Inform the SERU committees and research participants each time genetic analyses not only have implications for the relatives of the individuals undergoing testing, but for a community they may be identified with.

9.9 Ensure that adequate measures are in place for familial research so that study participants do not recruit other family members for the research or share confidential information amongst family members without explicit consent.

9.10 Provide a detailed description of the agreements between the investigators (local and international collaborators) made on access to and ownership of genetic information, findings or patents.

9.11 The provisions of benefit sharing with the community in which the research is conducted in terms of local training, technology transfer, improvement of health care and information infrastructure.

9.12 Disclose the results of the findings to research participants or their representatives who requests for the results or if it is part of clinical care of those individuals. If results will be

shared with the research participants or others, the PI/applicant should discuss the following in the application:

9.12.1 How research participants would benefit from the research results.

9.12.2 How predictive the tests are of the condition, disease, or genetic trait.

9.12.3 Whether the testing is available outside of the research context.

9.12.4 The measures in place to help ensure that the study results are contextualized appropriately for the study participant to understand and they have resource (e.g. genetic counselling) available to them should distress or anxiety occur associated with the research and the study results obtained. The expertise of the study staff responsible for educating and counselling research participants regarding the risks and benefits of the study must be clearly demonstrated in the curriculum vitae.

9.12.5 Disclose whether or not the genetic information will be placed in a medical record.

10. DETAILS OF PROCEDURE

10.1 The SERU committees shall review new proposed genetic-based studies at its next available meeting provided the research proposals or applications are received by the SERU Secretariat on or before the closing date

10.2 The SERU committees shall consider genetic research as any research conducted by investigators for the sole purpose of generating scientific knowledge about genes and/or the genetic basis of disease. This may include, but not limited to:

10.2.1 DNA diagnostic studies that determine the presence of specific mutations

10.2.2 DNA-based diagnostic tests that identify genes associated with specific medical conditions.

10.2.3 Paternity testing

10.2.4 Pedigree studies that investigate the inheritance of a particular trait or condition among related individuals or obtain information on family medical histories

10.2.5 Positional cloning studies that identify the location of specific genes

10.2.6 Gene therapy

10.2.7 The PI shall submit an informed consent document as per Appendix I

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of Genetic Research applications	Rejection of application by SERU Centre Compliance Officer	Principal Investigator submitting applications that do not meet criteria	Participating in training of principal investigator on submission of applications for genetic research

11.2 Opportunities

Process	Opportunity	Action plan to maximize the opportunity
Submission of Genetic Research applications	Training of principal investigator on submission of applications for genetic research	Scheduling regular trainings for KEMRI and Non KEMRI investigators

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 KEMRI SERU APP SOP_6.0 General Requirements of Informed Consent and Documentation of Informed Consent

12.2 External References

12.2.1 http://www.who.int/genomics/research/en/

12.2.2 http://www.nature.com/subjects/genetics-research

13. ANNEXES

13.1 Annex 1 - SERU Format and Content of an informed consent form for genetic studies

13.2 Annex 1 – SERU process flow

ANNEX I: SERU_FORMAT AND CONTENT OF AN INFORMED CONSENT FORM FOR GENETIC STUDIES

Title of the Research Study:
Investigator(s) – Local and international collaborators: Provide the name and institutional affiliation of all investigators on the study.

Study location: Indicate where the study will be conducted.

Purpose of the Research: Briefly describe the purpose of the genetic study in a language that should be understandable to the study population.

Procedures: Briefly describe how sample collection will be done, who will handle the sample(s), the location and duration of storage of the samples and indicate whether the study participant may be contacted in the future about the sample and/or study results.

Risks and Benefits: Briefly describe the common risks associated with sample collection and describe any potential risk if the genetic information is disclosed, either intentionally or inadvertently.

Confidentiality: Briefly describe the mechanisms that will be used to protect unauthorized access to the genetic material or information derived from it and the plans to destroy the sample in the future. Indicate whether the sample may be withdrawn at a later date if a study participant refrains from participating in the genetic aspect of a study.

Coding of samples: The type of coding of a sample must be specified because a sample that is anonymized cannot be withdrawn in the future.

Commercialization: The study participant(s) must be informed if there could be a potential for commercialization benefit from the results obtained using their sample. If that be the case, it must be clearly stated how the study participant, family or community stand to benefit.

All other elements of informed consent apply as per KEMRI SERU APP SOP_6.0 General Requirements of Informed Consent and Documentation of Informed Consent

ANNEX 2: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal Investigator	Submitting research related injury/harm applications	
Centre Compliance Officer	Receives, pre-reviews and records all research related injury/harm applications submitted to SERU